510(K) SUMMARY

K081524

JUL 29 2008

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Devices Act of 1990, 21 CFR 807.92.

Classification Name: Syringe, Piston

Common Name: Piston Syringe

Proprietary Name: SPECTRA-LOR, Loss of Resistance Syringe

Classification: Class II

Product Code: 80FMF

Regulation Number: 880.5860

Establishment Name, Contact & Registration Number:

Name:

Spectra Medical Devices, Inc.
260-F Fordham Road
Wilmington, MA 01887
Tele: 978-657-0889, Ext.
Fax: 978-657-4339

Contact: Scott Henderson

Intended Use:

The SPECTRA-LOR, Loss of Resistance Syringe is intended for use, in conjunction with an epidural needle, to verify the needle tip placement is in the epidural space by use of the Loss of Resistance Technique as detailed in medical textbooks and medical journal articles. The LOR Syringe is not intended for injection or aspiration.

Predicate Device: AVID-NIT Loss of Resistance Syringe, FDA 510(K) # K001731

Device Description:

The construction of the SPECTRA-LOR, Loss of Resistance Syringe is similar to that of a standard piston syringe; it has a barrel, a plunger and a bung. The barrel has graduations which correspond to a capacity of 10 ml and is available in a Luer Lock or Luer Slip tip.

510(K) SUMMARY
K

Equivalent Predicate Device:

The SPECTRA-LOR, Loss of Resistance Syringe is equivalent to the predicate device, AVID-NIT Loss of Resistance Syringe in materials of construction, intended use, capacity and bench testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Scott Henderson
International Engineering Manager
Spectra Medical Devices, Incorporated
4501 Greendale Drive
Williamsburg, Virginia 23188

JUL 29 2008

Re: K081524
Trade/Device Name: SPECTRA-LOR
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: May 30, 2008
Received: June 2, 2008

Dear Mr. Henderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K081524

Device Name: SPECTRA - LOR

Indications for Use:

The "SPECTRA – LOR", Loss of Resistance Syringe is intended for use, in conjunction with an epidural needle, to verify the needle tip placement in the epidural space by the Loss of Resistance technique as explained in standard medical textbooks. These syringes are not intended for injection or aspiration.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081524